

FDA-2636 Hospital Request for Methadone Detoxification Treatment.

(Approved by the Office of Management and Budget under number 0910-0140)

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## PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

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AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

SOURCE: 40 FR 14041, Mar. 27, 1975, unless otherwise noted.

### Subpart A—General Provisions

#### § 299.3 Definitions and interpretations.

(a) As used in this part 299, *act* means the Federal Food, Drug, and Cosmetic Act, sections 201-902, 52 Stat. 1040 (21 U.S.C. 321-392), with all amendments thereto.

(b) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part 299.

(c) The term *official name* means, with respect to a drug or ingredient thereof, the name designated in this part 299 under section 508 of the act as the official name.

#### § 299.4 Established names for drugs.

(a) Section 508 of the Federal Food, Drug, and Cosmetic Act (added by the Kefauver-Harris Drug Amendments of 1962; Pub. L. 87-781) authorizes the Commissioner of Food and Drugs to designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Section 502(e) of the act (as amended by said Drug Amendments) prescribes that the labeling of a drug must bear its established name, if there is one, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula) and, if the drug is fabricated from two or more ingredients, the es-

tablished name of each active ingredient.

(b) The term *established name* is defined in section 502(e)(3) of the act as (1) an official name designated pursuant to section 508 of the act; (2) if no such official name has been designated for the drug and the drug is an article recognized in an official compendium, then the official title thereof in such compendium; and (3) if neither paragraphs (b) (1) or (2) of this section applies, then the common or usual name of the drug.

(c) The Food and Drug Administration recognizes the skill and experience of the U.S. Adopted Names Council (USAN) in deriving names for drugs. The U.S. Adopted Names Council is a private organization sponsored by the American Medical Association, the United States Pharmacopeia, and the American Pharmaceutical Association, and has been engaged in the assignment of names to drugs since January 1964. The Council negotiates with manufacturing firms in the selection of nonproprietary names for drugs.

(d) The Food and Drug Administration cooperates with and is represented on the USAN Council. In addition, the Food and Drug Administration agrees with "Guiding Principles for Coining U.S. Adopted Names for Drugs," published in *USAN and the USP Dictionary of Drug Names* (USAN 1985 ed., 1961-1984 cumulative list), which is incorporated by reference. Copies are available from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or are available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. All applicants for new-drug applications and sponsors for "Investigational New Drug Applications" (IND's) are encouraged to contact the USAN Council for assistance in selection of a simple and useful name for a new chemical entity. Approval of a new-drug application providing for the use of a new drug substance may be delayed if a simple and useful nonproprietary name does not exist for the substance and if one is not proposed in the application that meets the above-cited guidelines. Prior use of a name in the medical literature or otherwise will not commit the Food